

## REMARKS

After entry of the present amendments Claims 1-19 and 21-26 will be pending. Claims 1, 10, 11, 19, and 21-24 are amended herein. Claims 1, 10, and 11 are amended to recite that the whey proteins are heat denatured at pH 6.0-7.0. Claim 20 is canceled herein. Claims 21 and 22 are adjusted to depend from Claim 18. Claims 23 and 24 are amended to remove "any one of". Support for the amendments can be found throughout the specification and claims as originally filed, in particular page 8 of the specification as originally filed. No new matter is added.

Applicants submit that this application is in condition for allowance and such action is earnestly requested. Each of the Examiner's reasons for rejection is addressed below.

### Claim Objections

The Examiner objected to the use of "any one of" in Claims 23 and 24. Claims 23 and 24 are amended herein to remove "any one of" thereby mooting this rejection.

### Rejections under 35 U.S.C. § 112

The Examiner objected to the use of "substantially nugget-free" in Claim 1. Applicants respectfully submit that the skilled artisan would understand the meaning of "substantially nugget-free". For example, Applicants submit that the skilled artisan would understand "substantially nugget-free" to mean either no nugget formation or minimal nugget formation. Accordingly, Applicants respectfully request withdrawal of this rejection.

### Rejections under 35 U.S.C. § 102

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

The Federal Circuit recently clarified the law of anticipation, stating that "[w]e thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed *but also all of the limitations arranged or combined in the same way as*

*recited in the claim*, it cannot be said to prove prior invention of the thing claimed and thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIn, Inc., v. Verisign, Inc.*, No. 2007-1565, slip opinion at pg. 17-18 (Fed. Cir. 2008) (emphasis added) (The Federal Circuit overturned the District Court’s finding of anticipation because the court found that neither of the two examples disclosed in the reference contained all of the elements arranged or combined as recited in the claim). “Differences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation.” *Id.* at pg. 18. The court further stated that:

Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. *See Arkley*, 455 F.2d at 587 (“[T]he [prior art] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.”).

*Net MoneyIn, Inc.*, No. 2007-1565, slip opinion at pg. 18-19 *citing In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (emphasis in original).

Applicants also note that “[i]nherency, however, may not be established by probabilities or possibilities. The fact that a given thing *may* result from a given set of circumstances is not sufficient.” *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). *See also Tintec Industries, Inc. v. Top-USA Corp.*, 63 U.S.P.Q.2d 1597, 1599 (Fed. Cir. 2002). When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added).

#### **Delespaul Does Not Anticipate Claims 1-11 and 25-26**

Claims 1-11 and 25-26 stand rejected under 35 U.S.C. § 102(b) as anticipated by FR 2452879 to Delespaul et al. (hereinafter “Delespaul”).

The present application is concerned with the problem of nugget formation in cheese when dried MPC and MPI are used and with the loss of whey proteins in the cheese-making process. The recited processes enhance the cold-solubility of the dried MPC or MPI by calcium

depletion and surprisingly the cold-solubility is not negated by denaturation of whey protein. Further, the process does not result in the inadequate solubility usually associated with denaturation. The denatured whey protein allows greater retention of protein with the curd in the cheese-making process.

Claims 1, 10, and 11, as amended herein, recite in part "wherein the whey proteins are heat denatured at pH 6.0-7.0". Delespaul does not disclose this feature as the Examiner found that Delespaul "is silent regarding using chelating agents for decalcification, or indirect means of heat treatment of the material, or a specific pH at which heat treatment is performed." Office Action, paragraph 23. Therefore, Delespaul fails to anticipate Claims 1, 10, and 11 for at least this reason. Accordingly, Applicants respectfully request withdrawal of this rejection.

Additionally, Applicants submit that Claims 2-9 are not anticipated by Delespaul, not only because they depend from Claim 1 but also on their own merit.

Further, Delespaul does not teach forming dried calcium-depleted, heat-treated MPC or its use in cheese manufacture. The Examiner found that "the prepared material can be in the form of liquid or powder, or can be reconstituted and have fat, standardized by skim milk, or mixed with materials of animal or plant origin. The material can include 0-75% dry matter and preferably 40-50% (page 3, lines 31-36)." The passage cited by the Examiner refers to the *raw materials* that can be processed by the methods disclosed by Delespaul on page 3:

The raw material can be in liquid form, a powder form, or it can be reconstituted and have a content of fatty substances, which is regulated by skimming or by the incorporation of animal and vegetal fatty substances, at approximately 0-75% with respect to the total dry extract, preferably approximately 40-50%.

The raw material is not decalcified, as it is subsequently passed over a cationic resin. There is no teaching of drying the processed material. Applicants also disagree with the finding in paragraph 17, "[g]iven that the ultrafiltered material as disclosed by [Delespaul] has 70% dry matter (Example 1, 2, 3), upon drying such a product will have dry matter, as milk protein, in the range as presently claimed."

Again, Delespaul does not teach forming dried MPC. Examples 1-3 disclose ultrafiltration of skim milk followed by various processing steps to make cheese products.

Examples 1-3 do not disclose forming dried MPC or processing of MPC, much less processing of HY-MPC.

Delespaul does not disclose “adding a 10-100% calcium depleted HY-MPC to milk containing fat or any other aqueous solution used as the starting material” as recited in Claim 10. Accordingly, Applicants request withdrawal of this rejection for at least this reason.

Delespaul does not disclose “dispersing in milk a dried HY-MPC having at least 70% SNF as milk protein” as recited in Claim 11. Accordingly, Applicants request withdrawal of this rejection for at least this reason.

Claim 25 recites “A dried HY-MPC having 20-100% depletion of calcium”. Delespaul fails to anticipate Claim 25 because it fails to teach a dried HY-MPC having 20-100% depletion of calcium. Additionally, Applicants submit that Claim 26 is not anticipated by Delespaul, not only because it depends from Claim 25 but also on its own merit.

Applicants also disagree with the Examiner’s finding that the cheese produced by Delespaul would inherently be substantially nugget free as presently claimed. As discussed above, Delespaul cannot solve the problem of nugget formation associated with the processing of dried MPC because Delespaul does not disclose processing dried MPC. Because Delespaul does not teach or suggest making cheese using a dried MPC, it cannot be inherent that a cheese made by such a process would be substantially nugget free. Thus, Applicants submit that the Examiner has not met the burden to show that this feature must necessarily flow from the teachings of Delespaul. Accordingly, Applicants respectfully request withdrawal of this rejection.

Further, this is more than an obvious variation of Delespaul because Delespaul does not disclose forming dried HY-MPC or even recognize the problem of nugget formation when using dried MPC, much less suggest the desirability of making cheese using dried HY-MPC.

**Rejections under 35 U.S.C. § 103(a)**

It is well settled that the Examiner “bears the initial burden of presenting a *prima facie* case of unpatentability...” *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or

evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also M.P.E.P. § 2143.02*.

And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F.3d 977, 988 (C.A.Fed.2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007).

Claims 7 and 12-24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Delespaul in view of WO 01/41578 to Bhaskar et al. (hereinafter "Bhaskar").

As discussed above, Delespaul does not teach forming dried MPC or dried HY-MPC. The Examiner found that Delespaul "is silent regarding using chelating agents for decalcification,

or indirect means of heat treatment of the material, or a specific pH at which heat treatment is performed.” Office Action, paragraph 23.

Applicants respectfully disagree with the combination suggested by the Examiner. The combination does not teach all of the features of the claims and there is no reason to use the heat treatment step disclosed in Delespaul with the process disclosed in Bhaskar.

Delespaul discloses a heat treatment step in the context of improving the texture of cheeses produced by ultrafiltration (“One object of the present invention is to improve the texture of the cheeses obtained by the ultrafiltration method” Delespaul, page 3). There is no teaching or suggestion of heat treatment of whey proteins. The process disclosed in Bhaskar focuses on preparation of calcium depleted MPC.

The combination suggested by the Examiner fails to teach the features recited in Claims 12 and 18. Claim 12 recites in part that the “heating at step (c) is carried out on a solution having a pH of 6.0-7.0.” Claim 18 recites in part “denaturing whey proteins in the calcium depleted product by heating the solution at pH 6.0-7.0 at a temperature, and for a time sufficient to allow denaturation of whey proteins, or by applying an ultra high pressure treatment” as recited in Claim 18. As acknowledged by the Examiner, Delespaul fails to teach a pH for the heat treatment it discloses. Bhaskar does not make up for this deficiency because Bhaskar does not teach a heat treatment step. To the extent Bhaskar discloses pH conditions for the calcium depletion step, this is unrelated to any heat treatment step, as there is no heat treatment step in Bhaskar. Further, there is no reason to apply the pH to the heat treatment of Delespaul, especially since Delespaul is concerned with avoiding too much denaturation. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

Moreover, even if the combination of Delespaul and Bhaskar is proper, one skilled in the art would have no reasonable expectation of success of modifying Bhaskar with a heat treatment step. *Pharmastem Therapeutics v. Viacell, Inc.* 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007) (after *KSR*, Federal Circuit finds claims non-obvious for lack of indication of reasonable expectation of success for asserted combination). Based on the teachings of Delespaul and Bhaskar, the skilled artisan would not reasonably expect that adding a heat treatment to the processes disclosed in Bhaskar would produce favorable results. The skilled artisan would expect denatured whey proteins to have poor cold solubility. Further, “[t]o the extent that an art

is unpredictable, as the chemical arts often are, *KSR*'s focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable." *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd*, Nos. 2007-1397, -1398, slip opinion at pg 8 (Fed Cir. 2008). Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

In addition, Delespaul teaches away from the combination because Delespaul cautions against excessive denaturing of the proteins ("This treatment, if pushed too far, unfortunately has the disadvantage of leading to excessive denaturing of the proteins and to a modification of the viscosity of the product." Delespaul, page 4).

Further, even if a prima facie case of obviousness was made it is rebutted by unexpected results. A problem with using MPC in cheese manufacture is that the whey proteins are in their native state. During curd formation these proteins stay in solution and are washed off with the whey. These proteins typically represent around 20% of the total milk proteins in the MPC. In addition, denatured whey proteins are known to have poor cold solubility. The claimed processes result in advantageous cold solubility of HY-MPC and allow for increased protein retention in cheese prepared with HY-MPC versus the use of MPC. See paragraph [0025] and FIGS. 4 and 5 of the specification as published. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

#### No Disclaimers or Disavowals

Although the present communication includes alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

**Application No.:** 10/540,829  
**Filing Date:** February 21, 2006

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: April 16, 2009

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